Supreme Court, U.S.
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No. 93-

IN THE

Supreme Court of the United States

October Term, 1993

JAMES ALBERT ELKINS, SR.; MARY JO ELKINS, as parents and natural guardians of JAMES ALBERT ELKINS, II,

Petitioners,

v.

RICHARDSON-MERRELL, INC.,

Respondent.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether a party may legitimately move for summary judgment under Fed. R. Civ. P. 56(c) based not on "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any" referenced by that rule, but instead based simply on the conclusory assertion that the non-moving party does not have sufficient evidence to support its case.

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OPINIONS BELOW

The opinion of the United States Court of Appeals for the Sixth Circuit (**A1-A9**[1]) is reported at 8 F.3d 1068. The opinion of the United States District Court for the Middle District of Tennessee (**A10-A13**) is unreported. The Report and Recommendation of the Magistrate Judge (**A14-A16**), recommending a grant of summary judgment, is unreported.

JURISDICTION

The decision of the court of appeals issued on October 20, 1993. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

PROCEDURAL RULE INVOLVED

Rule 56(c) of the Federal Rules of Civil Procedure provides, in relevant part:

> **Rule 56. Summary Judgment**
>
> **(c) Motion and Proceedings Thereon**. . . . The judgment sought shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. . . .

STATEMENT OF THE CASE

This Petition presents a square conflict in the circuits over the proper interpretation of *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986), concerning the burden facing a movant for summary judgment under Rule 56(c) of the Federal Rules of Civil Procedure. The Sixth Circuit, which affirmed the summary judgment below, reads *Celotex* as permitting a party to "move for summary judgment *asserting* that the opposing party will not be able to produce sufficient evidence at trial to withstand a

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[1] Page references to the appendices to this Petition are styled "**A**__."

directed verdict motion," and thereby to "challenge the opposing party to '*put up or shut up*' on a critical issue," so that if the opponent "[does] not 'put up,' summary judgment [is] proper." *Street v. J.C. Bradford & Co.*, 886 F.2d 1472, 1478 (6th Cir. 1989) (emphasis added). *See also* **A5-A6**; pp. 4-5, *infra*.

Other circuits have rejected this approach. The Eleventh Circuit, for example, has noted that *Celotex* is "commonly misunderstood and misapplied," and has held that "[e]ven after *Celotex* it is never enough simply to state that the non-moving party cannot meet its burden at trial." *Clark v. Coats & Clark, Inc.*, 929 F.2d 604, 607-08 (11th Cir. 1991). The Fifth Circuit has followed suit, praising the "thorough opinion" in *Clark* as exposing "a common misunderstanding of [*Celotex*]." *Russ v. International Paper Co.*, 943 F.2d 589, 591 (5th Cir. 1991), *cert. denied*, 112 S. Ct. 1675 (1992). The Fourth Circuit has also rejected the "put up or shut up" approach to summary judgment. *See Higgins v. Scherr*, 837 F.2d 155, 156-57 (4th Cir. 1988) ("the non-movant [is] not required to prove his entire case upon the mere incantation by [the movant] of 'summary judgment'").

This petition seeks review of this conflict among the circuits on a fundamental aspect of federal civil procedure.

1. Trial Court Proceedings. This is a products liability case falling under diversity jurisdiction and governed by Tennessee law. Petitioner James Albert Elkins, II was born on April 23, 1969, without legs, and missing portions of his right upper arm. Suit was filed on his behalf in the United States District Court for the Middle District of Tennessee, alleging that his limb defects had been caused by Bendectin, a prescription anti-nausea drug that was marketed by respondent Richardson-Merrell, Inc. ("Merrell"), which his mother took during the limb-development phase of her pregnancy. **A10**.

Merrell filed a motion for summary judgment, stating that "plaintiff cannot establish that Bendectin is capable of causing birth defects in general" and therefore that plaintiff could not

establish causation.[2] Rule 56(c) provides that summary judgment motions are decided on "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any." The only item on this list referenced by Merrell was the affidavit of an epidemiologist who, after analyzing a variety of epidemiological data, stated that "[b]ased upon these analyses, it is my opinion to a reasonable degree of medical and scientific certainty that maternal Bendectin ingestion is not associated with, and does not cause, limb reduction defects."[3]

Elkins opposed summary judgment on the strength of affidavits from several concededly qualified experts who had reached the conclusion, on this issue of general causation, that Bendectin *is* capable of causing birth defects. The district court, while assuming the admissibility of Elkins' evidence, granted summary judgment on the basis of two intervening Sixth Circuit decisions in cases with similar records, both concluding that the analysis contained in these experts' affidavits was insufficient to prove causation.[4]

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[2] Memorandum of Law in Support of Defendant Merrell Dow's Motion for Summary Judgment, dated June 21, 1991, at 3 (Sixth Cir. Joint Appendix ("**JA**") **70**).

[3] Affidavit of Dr. Steven H. Lamm, dated May 28, 1991, ¶ 10(e) (**JA 109**).

[4] After the summary judgment motion was briefed in the district court, the Sixth Circuit affirmed grants of summary judgment in Bendectin cases with similar records. *See Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349 (6th Cir.), *cert. denied*, 113 S. Ct. 84 (1992); *Lee v. Richardson-Merrell, Inc.*, No. 91-5369, 1992 U.S. App. LEXIS 8478 (6th Cir. April 22, 1992), *cert. denied*, 113 S. Ct. 197 (1992). On the strength of *Turpin* and *Lee*, the district court held that Elkins' expert affidavits on causation were insufficient to defeat summary judgment. *See* **A11-A12**. The Sixth Circuit agreed with this holding, **A2-A5**, a point on which Elkins does not now seek review in this Court.

2. The Decision on Appeal. While this case was pending on appeal, this Court handed down its decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786 (1993), addressing the rules for admissibility of expert scientific testimony. In relevant part, *Daubert* mandated that the testimony of a scientific expert is not admissible under Fed. R. Evid. 702 unless the expert demonstrates that the "reasoning or methodology underlying the testimony is *scientifically valid*." *Id.* at 2796 (emphasis added).

Elkins argued to the Sixth Circuit, in a supplemental brief and at oral argument, that summary judgment must be reversed because the sole record support cited by Merrell in its motion — the affidavit by its epidemiologist — was clearly inadmissible under *Daubert* on the record of this case.[5] Therefore, Elkins argued, Merrell had never met its burden of production under Rule 56(c) to "show" the court through reference to *some* material in the record that no genuine issue existed, so that it was left with the mere *conclusory assertion* that "plaintiff cannot establish that Bendectin is capable of causing birth defects in general." *See* p. 2, *supra*. Elkins cited *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 157 (1970), and *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986), as both holding that a non-movant has no obligation to respond unless and until the movant makes the required "show[ing]" by reference to record material.[6]

The Sixth Circuit took note of this argument and assumed that Merrell's sole affidavit could be found inadmissible under

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[5] *See* Letter Brief, dated July 26, 1993, at 1-5. Specifically, Elkins pointed out that the affidavit of Merrell's expert made no attempt to validate the methodology the expert had used, and that four of Elkins' experts had affirmatively attacked the methodology of Merrell's expert — that of relying *only* on epidemiological data to determine the risks posed by Bendectin, and ignoring three other types of data — as completely invalid. *Id.* at 3-4. For example, one expert stated: "it is *scientifically improper* to rely solely upon epidemiology studies to determine whether or not a drug is a teratogen." *Id.* at 4 (emphasis added) (quoting **JA 301**). Merrell made no response, either in writing or at oral argument, to this detailed demonstration of the invalidity of the methodology used by its only expert.

[6] *See id.* at 4-5 & n.1.

Daubert, but nevertheless held that Elkins had "misinterpreted the defendant's burden regarding summary judgment." **A5**. According to the Sixth Circuit, under Rule 56(c) a movant need *not* "show" the court the materials in the record demonstrating the absence of a genuine issue; it need only "point out the lack of a genuine issue" through a conclusory assertion to that affect. **A5-A6**. As support for the idea that such an assertion forces the non-movant to prove its case, the Sixth Circuit cited Rule 56(b) permitting motions to be made "with or without supporting affidavits" and, most critically, this Court's statement in *Celotex* that

> regardless of whether the moving party accompanies its summary judgment motion with affidavits, the motion may, and should, be granted so long as whatever is before the district court demonstrates that the standard for the entry of summary judgment, as set forth in Rule 56(c) is satisfied.

Celotex, *supra*, 477 U.S. at 323. *See* **A5**.

"Because Merrell does not bear the ultimate burden of persuasion on the causation issue," the court below held, Merrell had no burden to "show" the court anything in the record in order to win summary judgment under Rule 56(c):

> The reason for summary judgment was not the strength of the defendant's proof, but the insufficiency of the plaintiffs' proof. Thus, the admissibility of Merrell's affidavit under *Daubert* is irrelevant; the district court properly determined that the *plaintiffs* failed to demonstrate the existence of a genuine factual dispute regarding causation. The plaintiffs bear the burden of establishing causation. As a result, *Daubert* does not invalidate the district court's summary judgment analysis in this case.

A6 (emphasis in original).

REASONS FOR GRANTING THE WRIT

Review is warranted in this case to put an end to what the Fifth and Eleventh Circuits have correctly described, in detailed and cogent opinions, as a common misunderstanding of this Court's *Celotex* opinion: the idea that a conclusory assertion that the non-movant cannot win is enough to force the non-movant to "put up or shut up" and prove its case. Instead these circuits, along with the Fourth Circuit, cite the opinions of eight Justices in *Celotex* as making clear that the basic rule of *Adickes* remains unchanged: the movant must "show" from the sources listed in Rule 56(c) that no genuine issue appears to exist, based on the materials in the record. *See* cases cited at p. 2, *supra*; *see also United States v. Four Parcels of Real Property*, 941 F.2d 1428, 1437-38 & nn. 19-20 (11th Cir. 1991); *Fano v. O'Neill*, 806 F.2d 1262, 1266 (5th Cir. 1987).

The core holding of *Celotex*, on which eight Justices agreed, was that a movant is not necessarily required to file affidavits in order to "show" the absence of a genuine issue.[7] The only

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[7] *Celotex* clarified the nature of the moving party's burden by explaining that under Rule 56(c), if the moving party can establish its factual proposition "solely on the 'pleadings, depositions, answers to interrogatories, and admissions on file'" (the first four sources listed in Rule 56(c)), the moving party need not also produce an affidavit (the final source of proof listed in Rule 56(c)). *See* 477 U.S. at 324 (majority opinion) ("[i]n cases like the instant one, where the nonmoving party will bear the burden of proof at trial on a dispositive issue, a summary judgment motion may properly be made in reliance solely on the 'pleadings, depositions, answers to interrogatories, and admissions on file'") (quoting Rule 56(c)). *See also id.* at 328 (White, J., concurring) ("I agree that the Court of Appeals was wrong in holding that the moving defendant must *always* support his motion with evidence or affidavits . . . [and] I also agree that the movant may rely on depositions, answers to interrogatories, and the like, to demonstrate that the plaintiff has no evidence to prove his case and hence that there can be no factual dispute") (emphasis added); *id.* at 334 (Brennan, J., joined by Burger, C.J., and Blackmun, J., dissenting) ("I agree with the Court that . . . Celotex could seek summary judgment on the ground that plaintiff could not prove exposure to Celotex asbestos at trial").

Justice Stevens did not reach the issue of a movant's initial burden under Rule 56(c), arguing instead for an affirmance on a narrow factual ground and criticizing the views of the other eight Justices as an "abstract exercise in Rule construction." 477 U.S. at 339 (Stevens, J., dissenting).

disagreement among these Justices was about "the application of [Rule 56(c)'s framework] to the facts of this case." 477 U.S. at 334 (Brennan, J., joined by Burger, C.J., and Blackmun, J., dissenting).

To be sure, the majority opinion in *Celotex* did observe, in a passage cited by the Sixth Circuit below, that summary judgment should be decided based on "whatever is before the district court," arguably suggesting that a conclusory assertion is enough to satisfy a party's Rule 56(c) burden. *See id.* at 323; p. 5, *supra*. In conflict with that interpretation, however, is the statement at the beginning of the same paragraph that, "[o]f course, a party seeking summary judgment always bears the initial responsibility of . . . identifying those portions of the [record] which it believes demonstrate the absence of a genuine issue of material fact." *Id.* In light of such imprecision, three Justices complained in *Celotex* that "the Court has not clearly explained what is required of a moving party seeking summary judgment on the ground that the non-moving party cannot prove its case," and they predicted that "the Court's opinion will very likely create confusion." *Id.* at 329 (Brennan, J., joined by Burger, C.J., and Blackmun, J., dissenting).

This prediction was certainly accurate. Despite the clarifying opinions accompanying the majority opinion in *Celotex*,[8] the case is commonly misunderstood as holding that a conclusory

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[8] Justice White, who provided the fifth vote for the majority's result on the facts of the case, noted that "the movant must discharge the burden the Rules place upon him: It is not enough to move for summary judgment without supporting the motion in any way or with a *conclusory assertion* that the plaintiff has no evidence to prove his case." 477 U.S. at 328 (White, J., concurring) (emphasis added). The three other Justices who addressed the point observed: "If there is literally no evidence in the record, the moving party may demonstrate this by reviewing for the court the admissions, interrogatories, and other exchanges between the parties that are in the record. Either way, however, the moving party must *affirmatively* demonstrate that there is no evidence in the record to support a judgment for the nonmoving party. If the moving party has not fully discharged this initial burden of production, its motion for summary judgment must be denied, and the Court need not consider whether the moving party has met its ultimate burden of persuasion." *Id.* at 332 (Brennan, J., joined by Burger, C.J., and Blackmun, J., dissenting) (emphasis added) (citation omitted).

assertion that the other party cannot prove its case is enough to force a response, a point that the Fifth and Eleventh Circuits have both noted. *See* p. 2, *supra*. Indeed, one study of federal summary judgment opinions citing *Celotex* revealed that by and large "courts are not reviewing the sufficiency of the defendant/movant's production": in *60 percent* of cases in which summary judgment was granted, there was *no* "discussion of the sufficiency of the defendant's production in support of the summary judgment motion." Samuel Issacharoff and George Loewenstein, *Second Thoughts About Summary Judgment*, 100 YALE L.J. 73, 91-92 (1990). Even the D.C. Circuit, from which *Celotex* originated, has ignored the movant's burden in at least one case. *See ACLU Foundation of Southern California v. Barr*, 952 F.2d 457, 469 (D.C. Cir. 1991) (stating that movant "need only assert that plaintiffs do not have sufficient evidence to carry their burden of proving" the fact at issue).[9]

The widespread confusion in the lower courts over *Celotex*, and the circuit conflict it has engendered, are reason enough for this Court to grant review in order to clarify the nature of a movant's summary judgment burden. But the danger posed by the decision below to fairness and efficiency in the administration of justice is a final ground for review.

As Dean Friedenthal has observed, presumably it would be constitutionally permissible to "require a party with the burden of proof . . . to make a pretrial showing that it could support its case with some evidence," either in every case, or on the demand of the opponent. Jack H. Friedenthal, *Cases on Summary Judgment: Has There Been a Material Change in Standards?*, 63

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[9] Indeed, even the Sixth Circuit appears confused about the meaning of *Celotex*. In two decisions rendered prior to the decision below, it has applied Rule 56(c) correctly. *See Wilson v. City of Zanesville*, 954 F.2d 349, 350-51 (6th Cir. 1992) ("the movant must always bear this initial [Rule 56(c)] burden, whether or not the adverse party responds," and "the court must examine the movant's motion for summary judgment to ensure that he has discharged that burden"); *Carver v. Bunch*, 946 F.2d 451, 454-55 (6th Cir. 1991) ("the requirement that the movant bears the initial burden has remained unaltered" by *Celotex*). Both decisions were cited to the Sixth Circuit below, which inexplicably ignored them.

NOTRE DAME L. REV. 770, 772 (1988). But "[w]hether or not we would want to inaugurate such a 'put up or shut up' procedure" as a matter of policy is another question. *Id.* Permitting the Sixth Circuit and other courts to continue with their "put up or shut up" approach would be "extremely wasteful": "If one party could, merely by filing an unsupported motion, force an opponent to make a substantial showing, there would be a strong incentive to make such a filing, if for no other reason than to harass the other party and raise its costs of litigation." *Id.* at 776.[10]

After all, "[t]he purpose of summary judgment is to save courts and litigants from the burdens of trying cases where no genuine dispute exists, not to raise the stakes by meaningless procedural devices." *Id.* at 776-77. From an efficiency perspective, there appears to be ample reason to believe that the rule followed by the Sixth Circuit "will likely increase aggregate legal expenditures, thus producing a corresponding deadweight loss to society." Issacharoff and Loewenstein, *supra*, 100 YALE L.J. at 103. Regardless of how these policy issues might be resolved by Congress and the rulemakers, given the present Rule 56(c) it is clear that the Sixth Circuit and the other courts currently following the "put up or shut up" rule are misguided, and should be corrected through this Court's prompt intervention.

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[10] Another scholar has addressed the point in pragmatic terms:

> The Constitution aside, look at the practical position of plaintiffs. Something close to a one page form motion by defendant can throw on the plaintiff the responsibility to dredge, structure, collate and cross-reference all materials in the file to make them available to the judge before trial. Because the material must be reduced to a coherently structured written form, this task can sometimes take as long or longer than actually trying the case. And if this task is done with less than complete thoroughness, since the judge has no other access to the potential record material, the result will be not merely a finding that the record cannot confidentially be predicted, but the entry of judgment for the defendant.

D. Michael Risinger, *Another Step in the Counter-Revolution: A Summary Judgment on the Supreme Court's new Approach to Summary Judgment*, 54 BROOKLYN L. REV. 35, 41-42 (1988).

CONCLUSION

For all these reasons, certiorari should be granted.

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APPENDICES

APPENDIX A

Decision of the United States Court of Appeals for the Sixth Circuit, dated October 20, 1993 . . . . . **A1**

APPENDIX B

Decision of the United States District Court for the Middle District of Tennessee, dated July 31, 1992 . . . **A10**

APPENDIX C

Report and Recommendation of the United States Magistrate Judge to the United States District Court for the Middle District of Tennessee, recommending a grant of summary judgment, dated March 19, 1992 . . . **A14**

APPENDIX A

UNITED STATES COURT OF APPEALS
For the Sixth Circuit

No. 92-6172

JAMES A. ELKINS, SR.; MARY JO ELKINS; JAMES A. ELKINS, II, *Plaintiffs*, JAMES ELKINS, JR., *Plaintiff-Appellant*, v. RICHARDSON-MERRELL, INC., *Defendant-Appellee*.

On Appeal from the United States District Court for the Middle District of Tennessee.

Decided and Filed October 20, 1993

Before: GUY and NELSON, Circuit Judges; and WELLFORD, Senior Circuit Judge.

HARRY W. WELLFORD, Senior Circuit Judge. Once again this court considers a product liability action alleging that Bendectin, a drug manufactured by Richardson-Merrell, Inc., (RMI), caused a severe birth defect. The district court granted summary judgment in RMI's favor based on the similarity between this case and two recent Bendectin cases in this circuit, both of which ended in summary judgment for the defendant. *Lee v. Richardson-Merrell, Inc.*, 772 F. Supp. 1027 (W.D. Tenn. 1991), *aff'd, mem.*, 961 F.2d 1577 (6th Cir.), *cert. denied*, 113 S. Ct. 197 (1992); *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 736 F. Supp. 737 (E.D. Ky. 1990), *aff'd*, 959 F.2d 1349 (6th Cir.), *cert. denied*, 121 L. Ed. 2d 47, 113 S. Ct. 84 (1992). The plaintiff now appeals the entry of summary judgment against him.

I.

Bendectin has been approved by the FDA for the purpose of combatting morning sickness since 1956. Faced with costly litigation involving the use of Bendectin, however, Merrell-Dow

voluntarily withdrew the drug from the market in 1983. Notwithstanding Bendectin's withdrawal from the marketplace, the FDA has maintained its support of Bendectin as a safe and effective drug for the purpose of relieving nausea and vomiting associated with pregnancy. Moreover, comparison studies have failed to detect any significant reduction in the incidence of birth defects since Bendectin became unavailable in 1983.

The proof in this case is identical to the proof offered in the two other recent Bendectin cases in this circuit--*Turpin* and *Lee*.[1] In all three cases, as in myriad Bendectin cases in other circuits, the plaintiffs rely on *in vitro* (in the test tube) studies, *in vivo* (animal) studies, and reanalyses of human epidemiological studies. The defendants, on the other hand, rely on more than 30 human epidemiological studies, all of which concluded that there was no identifiable link between Bendectin and birth defects.[2] Relying almost exclusively on *Turpin*, the magistrate

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[1] In their unsuccessful motion for consolidation, the plaintiffs asserted that:

> [d]iscovery of all of the defendant's witnesses has been essentially completed except for a few experts. In the *Lee* case and it is anticipated that the same witnesses will be utilized in the *Elkins* case. [sic.] On the other hand, all of the plaintiffs' witnesses in the *Elkins* and *Lee* cases will be the same except for some brief individual witnesses on damages and the parents.

Elkins v. Richardson-Merrell, Inc., No. 3:91-0167, slip. op. at 4. In *Lee v. Richardson-Merrell, Inc.*, 961 F.2d 1577 (6th Cir. 1992)(unpublished), slip. op. at 2-3, this court noted that "the evidence presented by the Lees in the instant case is identical in all material respects to the evidence relied upon by the plaintiffs in [*Turpin v. Merrell-Dow Inc.*, 959 F.2d 1349 (6th Cir.) *cert. denied*, 113 S. Ct. 84 (1992)]." Thus, the evidence presented in *Elkins*, *Lee*, and *Turpin* is indistinguishable in any material respect.

[2] For purposes of this case, a technical analysis of the plaintiff's proof is unnecessary. Judge Merritt engaged in a thorough analysis of the studies exploring the possible connection between Bendectin and birth defects in *Turpin*, 939 F.2d at 1353-60. A detailed analysis of the methodology behind the studies appeared in a recent Third Circuit case, *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 945-49 (3d Cir. 1990).

recommended that summary judgment be issued in Merrell's favor. The district court found "no material differences" between *Elkins* and *Lee*, and, relying also on *Turpin*, accepted the magistrate's recommendation.

The plaintiff argues on appeal that under the United States Supreme Court's recent decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786 (1993), the scientific opinions offered by the defendant's expert witness were inadmissible; that the defendant therefore failed to show the absence of a genuine issue of material fact; that under Tennessee law, which must be applied here pursuant to *Erie Railroad v. Tompkins*, 304 U.S. 64 (1938), it was error for the district court to take a "hard look" at the basis for the scientific theories and inferences embodied in the plaintiffs' affidavits, and that the district court violated the Seventh Amendment by failing to preserve the plaintiffs' right to trial by jury.

II.

In *Turpin v. Merrell-Dow, Inc.*, 959 F.2d 1349 (6th Cir.), *cert. denied*, 113 S. Ct. 84 (1992), we dealt at length with the difficult issues attending the nature of proof presented by plaintiffs in Bendectin actions like this one. In an opinion authored by Chief Judge Merritt, this court affirmed the district court's grant of summary judgment, based on the weakness of the causal link between Bendectin and birth defects. We held that:

> Based on the record before us, . . . whether Bendectin caused the minor plaintiff's birth defects is not known and is not capable of being proved to the requisite degree of legal probability based on the scientific evidence currently available. Taken in the light most favorable to the plaintiffs, the scientific evidence that provides the foundation for the expert opinion on causation in this case is not sufficient to allow a jury to find that it is more probable than not that Bendectin caused the minor plaintiff's injury.

Turpin, 959 F.2d at 1350.[3]

In Turpin, we found additional authority supporting the view of the court: *Wilson v. Merrell Dow Pharmaceuticals*, 893 F.2d 1149, 1154 (10th Cir. 1990) (finding "particularly significant" the "absence of epidemiological evidence showing a causal relationship between Bendectin and birth defects"); *Brock v. Merrell Dow Pharmaceuticals*, 874 F.2d 307, 315, (5th Cir. 1989), *cert. denied*, 494 U.S. 1046 (1990) (verdict for plaintiff set aside by j.n.o.v.--"we are convinced that the Brocks did not present sufficient evidence regarding causation to allow a trier of fact to make a reasonable inference that Bendectin caused Rachel Brock's limb reduction defect"). We also considered *Daubert v. Merrell Dow Pharmaceuticals*, 951 F.2d 1128 (9th Cir. 1981), and *DeLuca v. Merrell Dow Pharmaceuticals*, 911 F.2d 941 (3d Cir. 1990), in *Turpin*.

We construe *Turpin* to treat the plaintiff's expert opinion indicating a basis of support for the plaintiffs' theories in animal studies to be admissible but "simply inadequate . . . [to] permit a jury to conclude that Bendectin more probably than not causes limb defects." *Id.* at 1360. This court found the evidence to be admissible, we believe, but that it presented too wide an "analytical gap" for reasonable inferences on causation "to be drawn on the ultimate issue of human birth defects." *Turpin*, 959 F.2d at 1360. As we have already indicated, the evidence offered by *Elkins* does not differ in any material respect from evidence presented in both *Turpin* and *Lee*. We agree with the district court that this case is factually indistinguishable from *Turpin* and *Lee*. Thus, unless the plaintiffs have demonstrated some reason,

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[3] In *Turpin* and in *Lee*, seven different judges sitting on this court have adhered substantially to this view expressed by Chief Judge Merritt. The panel in this case consists of three additional Sixth Circuit judges. We do not count in this number the three different additional judges on this court who considered and affirmed the class action jury verdict for the defendant on the issue of causation of human birth defects by ingestion of Bendectin. *In re Bendectin Litigation*, 857 F.2d 290 (6th Cir. 1988), *cert. denied sub. nom. Hoffman v. Merrell Dow Pharmaceuticals, Inc.*, 488 U.S. 1006, (1989).

aside from any factual argument, why those cases should not apply here, *Turpin* and *Lee* control this case, and mandate summary judgment in Merrell's favor.

A.

The plaintiff argues that, considering the Supreme Court's recent decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786 (1993), the defendants failed to meet their burden, under Rule 56(c), of showing, "that there is no genuine issue as to any material fact and that [Merrell] is entitled to a judgment as a matter of law." Fed R. Civ. P. 56(c). Under *Daubert*, the plaintiffs contend, the only affidavit used to support the defendant's motion for summary judgment has not been shown admissible. Thus, the plaintiffs argue that summary judgment must be reversed, or in the alternative, that remand is necessary, so the district court may determine, consistent with *Daubert*, whether the defendant's affidavit is admissible.

The plaintiff has misinterpreted the defendant's burden regarding summary judgment. Because Merrell does not bear the ultimate burden of persuasion on the causation issue, Merrell need only point out the lack of a genuine issue regarding causation. *See, Calderone v. United States*, 799 F.2d 254, 259 (6th Cir. 1986)("when the moving party does not have the burden of proof on the issue, he need show only that the opponent cannot sustain his burden at trial.") Moreover, Merrell had no obligation to support its motion for summary judgment with *any* affidavits. Rule 56 provides that a defending party may "move *with or without supporting affidavits* for summary judgment in the party's favor." Fed. R. Civ. P. 56(b) (emphasis added). As the Supreme Court has explained,

> regardless of whether the moving party accompanies its summary judgment motion with affidavits, the motion may, and should, be granted so long as whatever is before the district court demonstrates that the standard for the entry of summary judgment, as set forth in Rule 56(c) is satisfied.

Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986).

Merrell pointed out the absence of a genuine factual issue on the material element of causation. The district court agreed that the plaintiffs had failed to establish a genuine factual dispute regarding causation. In doing so, the court relied on *Turpin*, where this court determined that, even

> [t]aken in the light most favorable to the plaintiffs, the scientific evidence that provides the foundation for the expert opinion on causation in this case is not sufficient to allow a jury to find that it is more probable than not that Bendectin caused the minor plaintiff's injury."

Turpin, 959 F.2d at 1350. The reason for summary judgment was not the strength of the defendant's proof, but the insufficiency of the plaintiffs' proof. Thus, the admissibility of Merrell's affidavit under *Daubert* is irrelevant; the district court properly determined that the *plaintiffs* failed to demonstrate the existence of a genuine factual dispute regarding causation. The plaintiffs bear the burden of establishing causation. As a result, *Daubert* does not invalidate the district court's summary judgment analysis in this case.

B.

Even though the plaintiff concedes that he relies on "evidence similar to that found in *Turpin* and *Lee*," he argues that Tennessee law, not federal law, is controlling under *Erie Railroad v. Tompkins*, 304 U.S. 64 (1938), and specifically, that this court adopts state law when ruling on summary judgment motions in diversity cases, citing *McDonald v. Union Camp Corp.*, 898 F.2d 1155, 1163 (6th Cir. 1990), and *Bank of Cumberland v. Aetna Casualty Co.*, 956 F.2d 595, 597 (6th Cir.), *cert. denied*, 113 S. Ct. 204 (1992), among others.[4] They contend that *Turpin*'s instruction to take a "hard look" at the

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[4] While we are merely reciting the plaintiffs' argument here, we note that the cases relied upon by the plaintiffs in their brief as to the sufficiency of the evidence deal with directed verdicts and judgments notwithstanding the verdict, not summary judgment.

basis for scientific opinions is at odds with Tennessee law regarding summary judgment. *See Turpin*, 959 F.2d at 1352. Consequently, they argue, the district court violated the *Erie* doctrine by relying on *Turpin*.

The defendant responds that the plaintiff has failed to raise this issue prior to appeal. In Elkins' objections to the magistrate judge's recommendation that summary judgment be granted to the defendant, the plaintiff mentioned: (1) "the Seventh Amendment;" (2) "all of the Rules of Evidence;" (3) a petition for certiorari pending in *Turpin*; (4) confusion of the "issue of res judicata and collateral estoppel with stare decisis;" (5) "lack of wisdom of the Opinion in *Turpin*;" (6) "all of the science that is involved [should be considered] in order to reach a conclusion;" (7) defendant's drug is a teratogen, and . . . caused the defect in this case;" (8) methodology of the parties' experts is the same; and (9) "only the conclusions of the experts differ." Conspicuous by its absence from this list was any mention of state law evidential requirements as to the summary judgment, or any mention of *Erie Railroad* requirements. Moreover, the district judge mentioned nothing in his memorandum opinion overruling the plaintiff's objections about applying state law or *Erie Railroad*. The plaintiffs sought no reconsideration or clarification of this decision based upon the district court's overlooking any argument such as is now advanced. This court does not normally address issues raised for the first time on appeal. *Taft Broadcasting Co. v. United States*, 929 F.2d 240, 243-45 (6th Cir. 1991); *White v. Anchor Motor Freight, Inc.*, 899 F.2d 555, 559 (6th Cir. 1990). While this rule is discretionary, the court has adhered to the rule except in "'exceptional cases or particular circumstances' or when the rule would produce 'a plain miscarriage of justice.'" *Pinney Dock and Transp. Co. v. Penn Cent. Corp.*, 838 F.2d 1445, 1461 (6th Cir.) *cert. denied*, 488 U.S. 880 (quoting *Hormel v. Helvering*, 312 U.S. 552, 557-58 (1941)). This case does not present the kind of exceptional circumstances that warrant disregarding the general rule. Because the plaintiffs did not adequately raise the *Erie Railroad* argument before the district court, we decline to consider that issue for the first time on appellate review.

C.

The plaintiff's final argument is that *Turpin* requires a court to weigh the credibility of the evidence when ruling on a summary judgment motion, and that this practice violates the Seventh Amendment right to a jury trial. We disagree.

Noting the "difficulty . . . in knowing what reasonable inferences of causation to draw from animal experiments and epidemiological studies" and the "uncertainty of judges about how far they should enter the scientific thicket of conflicting inferences in order to determine whether the basis of a scientific opinion concerning causation is significantly plausible to allow a jury to ground a verdict on it," Judge Merritt's opinion in *Turpin* instructed district judges to take a "hard look" at the basis of scientific opinions. *Turpin*, 959 F.2d at 1352. The court held that "close judicial analysis of . . . technical and specialized matter" is necessary not only to control juror misunderstanding, but also to curtail "the potential for exaggeration and fraud on the court, [which is often] impossible to discover without close inspection and careful consideration of the record." *Id.* at 1352-53.

The direction to take a "hard look" at the basis of a scientific opinion does not require weighing credibility any more than the Supreme Court's direction to consider the record as a whole and decide whether any rational juror could decide the disputed factual issue in the plaintiff's favor. *See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (summary judgment is appropriate "where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party"); *Street v. J.C. Bradford & Co.*, 886 F.2d 1472, 1480 (6th Cir. 1989) (same). Moreover, the Supreme Court recently cited *Turpin* with approval as a preferred method of dealing with weak scientific proof in Bendectin cases. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786, 2798 (1993). Significantly, the Court in *Daubert* indicated that even if expert opinion or evidence on one side were relevant and admissible, if "insufficient to allow a reasonable juror to conclude that the position more likely than not is true," it may be the basis for a directed verdict or a grant of summary judgment.

Id. at 8. Following this last observation, the Court added:

> *Cf.*, e.g., *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349 (CA6) ("holding that scientific evidence that provided foundation for expert testimony, viewed in the light most favorable to plaintiffs, was not sufficient to allow a jury to find it more probable than not that defendant caused plaintiff's injury), *cert. denied*, 506 U.S. 1992); *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307 (CA5 1989) (reversing judgment entered on jury verdict for plaintiffs because evidence regarding causation was insufficient), *modified*, 884 F.2d 166 (CA5 1989), *cert. denied*, 494 U.S. 1046 (1990). . . ."

Id. at 9. Thus, we do not believe that the prophylactic measure adopted in *Turpin* violates the Seventh Amendment.

III.

As we have repeatedly indicated, we agree with the district court that this case is indistinguishable from *Turpin* and *Lee*, both factually, and regarding the scientific evidence presented. We deem that *Daubert* does not require a remand for the reasons herein pointed out. Because the plaintiffs did not adequately raise the *Erie Railroad* argument before the district court, we decline to consider that issue for the first time on appeal. Finally, we do not believe that the *Turpin* hard look analysis violates the Seventh Amendment. Consequently, the plaintiff has failed to demonstrate any reason why reliance on *Turpin* and *Lee* as controlling precedent is improper. For the reasons we have indicated, then, we **AFFIRM** the district court.

APPENDIX B

UNITED STATES DISTRICT COURT
For the Middle District of Tennessee
Nashville Division

No. 3:91-0167
Judge Higgins

JAMES ALBERT ELKINS, SR., et al.
v. RICHARDSON-MERRELL, INC.

July 31, 1992

MEMORANDUM

The Court has before it the Report and Recommendation of the Magistrate Judge (entered March 19, 1992; Docket Entry No. 31), the plaintiff's objections thereto (filed April 7, 1992; Docket Entry No. 33), and the defendant's response to the plaintiff's objections (filed April 15, 1992; Docket Entry No. 35). After having reviewed the entire record, and for the reasons stated below, the Court adopts and approves the Report and Recommendation in all regards. The plaintiff's objections are overruled. Therefore, the defendant's motion for summary judgment (filed June 24, 1991; Docket Entry No. 14) shall be granted.

I. DISCUSSION

This action was filed by James Albert Elkins, Sr., and Mary Jo Elkins, individually and as parents and natural guardians of James Albert Elkins, II. The plaintiffs allege that Mary Jo Elkins took the prescription drug Bendectin, which was manufactured by the defendant, to treat the symptoms of morning sickness while pregnant. They further allege that James Elkins, II, was born with severe birth defects because of his mother's ingestion of Bendectin while pregnant.

The claims of the plaintiffs, James Elkins, Sr., and Mary Jo Elkins, were dismissed with prejudice by stipulation. *See* stipulation of dismissal (entered May 17, 1991; Docket Entry

No. 7); Order (entered June 27, 1991; Docket Entry No. 18). Therefore, only the claims of James Elkins, II, remain. The defendant Merrell filed its motion for summary judgment on June 24, 1991 (Docket Entry No. 14), arguing that

> there is no admissible evidence sufficient to raise a triable issue of fact as to whether Bendectin is capable of causing birth defects. Since plaintiff cannot establish that Bendectin is capable of causing birth defects in general, he cannot, as a matter of law, establish that Bendectin was a proximate cause of his birth defects.

Memorandum of law in support of defendant Merrell Dow's[1] motion for summary judgment at 3 (filed June 24, 1991; Docket Entry No. 16).

The Magistrate Judge recommended granting Merrell's motion for summary judgment, based on the similarities between this case and the recently decided case of *Turpin v. Merrell-Dow Pharmaceuticals, Inc.*, 959 F.2d 1349 (6th Cir., 1992). Report and Recommendation at 2-3. In *Turpin*, the Sixth Circuit Court of Appeals exhaustively discussed the wealth of scientific studies, proffered by both parties, which have been performed to determine whether Bendectin causes birth defects. *See Turpin*, 959 F.2d 1349, 1353-1359. The Court of Appeals affirmed the decision of the district court to grant summary judgment for the defendant, concluding that

> the plaintiffs' experts stop short of testifying that Bendectin more probably than not caused the birth defects in babies. They stop short because they have no factual or theoretical basis for a stronger hypothesis.
>
> . . . .
>
> The analytical gap between the evidence presented and the inferences to be drawn on the ultimate issue of human birth defects is too wide. Under such circumstances, a

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[1] Merrell-Dow has changed its name to Richardson-Merrell and will be referred to as "Merrell" throughout this memorandum.

> jury should not be asked to speculate on the issue of causation.

Id., at 1349. Thus, the Court did not rule out the possibility that Bendectin may be proven to cause birth defects in humans. It merely concluded that the evidence before it was not sufficient to allow the jury to decide the issue of causation. *See id.* 959 F.2d 1349, slip op. at 22.

Similarly, in *Lee v. Richardson-Merrell*, No. 91-5369 (6th Cir., April 22, 1992) (unpublished disposition), another panel of the Sixth Circuit affirmed the district court's grant of summary judgment in favor of the defendant, concluding "that a finding of a causal relationship between Bendectin use and [the injured plaintiff's] birth defects based upon this evidence would be conjectural at best in light of this court's recent opinion in [*Turpin*]." *Id.*, slip op. at 3. The *Lee* case is virtually identical to this case. In the memorandum in support of the motion to consolidate the two cases, the plaintiffs stated that "the complaints [in the *Lee* and *Elkins* cases] are nearly identical in substance. . . ." Memorandum of points and authorities in support of plaintiffs' motion to consolidate at 1, filed as exhibit 1 to the supplement to the memorandum in support of Merrell's motion for summary judgment (filed May 12, 1992; Docket Entry No. 36). The plaintiffs also asserted as grounds for consolidation that

> [d]iscovery of all of the defendant's witnesses has been essentially completed except for a few experts. In the *Lee* case and it is anticipated that the same witnesses will be utilized in the *Elkins* case. [Sic.] On the other hand, all of the plaintiffs' witnesses in the *Elkins* and *Lee* cases will be the same except for some brief individual witnesses on damages and the parents.

Id. at 2. Given the admitted similarity between the *Lee* case and this case, and having found no material differences in the two cases during its own review, the Court grants Merrell's motion for summary judgment.

II. CONCLUSION

For the reasons stated above, the Court adopts and approves the Magistrate Judge's Report and Recommendation in all regards. Therefore, the defendant's motion for summary judgment shall be granted.

An appropriate order shall be entered.

(signed)_____
Thomas A. Higgins
United States District Judge
July 31, 1992

ORDER

In accordance with the memorandum contemporaneously entered, the Report and Recommendation of the Magistrate Judge (entered March 19, 1992; Docket Entry No. 31) is adopted and approved in all regards. The plaintiff's objections thereto (filed April 7, 1992; Docket Entry No. 33) are overruled.

Therefore, the defendant's motion for summary judgment (filed June 24, 1991; Docket Entry No. 14) is granted. All issues before the Court having been disposed on their merits, this case is dismissed with prejudice.

It is so ORDERED.

(signed)_____
Thomas A. Higgins
United States District Judge
July 31, 1992

APPENDIX C

IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

No. 3:91-0167
Judge Higgins

JAMES ALBERT ELKINS, SR., et al.
v. RICHARDSON-MERRELL, INC.

March 19, 1992

REPORT AND RECOMMENDATION

I. INTRODUCTION

This civil action was referred to the Magistrate Judge by the Honorable Thomas A. Higgins, District Judge by Order entered August 9, 1991 (Docket Entry No. 25). Pursuant to 28 U.S.C. § 636(b)(1)(B), the Magistrate was directed to consider, submit proposed findings of fact and make recommendations for disposition as to the following motion. Pending before the Court is defendant's motion for summary judgment (Docket Entry No. 14).

Plaintiffs, James Elkins, Sr. and Mary Jo Elkins, individually and as parents and guardians of James Albert Elkins II, Tennessee citizens, filed this action under 28 U.S.C. § 1332, the federal diversity statute, against defendant Merrell Dow Pharmaceuticals, Inc. (formerly Richardson-Merrell, Inc. and hereinafter "Merrell"), a Delaware corporation with its principal place of business in Ohio. Merrell manufactured and sold the drug Bendectin from 1956 to 1983. Bendectin is designed to treat the "morning sickness" which pregnant women suffer. Mary Jo Elkins took this drug while carrying plaintiff James Albert Elkins II ("Elkins"). Elkins was subsequently born with severe birth defects.

On October 31, 1991, the Magistrate recommended that consideration of the pending motion be stayed pending the Court of Appeals' ruling on an appeal from *Turpin v. Merrell Dow Pharmaceuticals*, 736 F.Supp. 737 (E.D. Ky. 1990). (Docket Entry No. 29). On January 28, 1992, the Court adopted this recommendation. (Docket Entry No. 30).

On March 11, 1992, the Court of Appeals affirmed summary judgment for Merrell. *See Turpin v. Merrell Dow Pharmaceuticals, Inc.*, No. 90-5690 (6th Cir., March 11, 1992) (*slip op.*) (a copy of which is attached hereto). The Court of Appeals held that epidemiological evidence was not conclusive on the issue of causation. *Id.* at 17. On the other hand, the Court of Appeals considered plaintiff's evidence and concluded that "the factual and theoretical bases articulated for the scientific opinions stated will not support a finding that Bendectin more probably than not caused the birth defect here." *Id.* at 22. The Court of Appeals held that the animal studies relied upon by plaintiff's experts did not prove causation in humans.

> Here, the record's explanation of the animal studies is simply inadequate. Although the animal studies themselves may have been scientifically performed, the exact nature of these tests is explained only in general terms. The record fails to make clear why the varying doses of Bendectin or doxyalamine succinate given to the rats, rabbits and *in vitro* animal cells would permit a jury to conclude that Bendectin more probably than not causes limb defects in children born to mothers who ingested the drug at prescribed doses during pregnancy. The analytical gap between the evidence presented and the inferences to be drawn on the ultimate issue of human birth defects is too wide. Under such circumstances, a jury should not be asked to speculate on the issue of causation.

Id. at 24.

The Magistrate notes that the evidence submitted in *Turpin* is virtually identical to the evidence in this action. The *Turpin* plaintiff also suffered limb deformities in circumstances which are similar to the ones at issue here. *See id.* at 3.

Accordingly, the Magistrate recommends that Merrell's motion for summary judgment be granted. If there are any meaningful distinctions between the present case and *Turpin*, the parties may raise them in their objections to this Report and Recommendation. The Magistrate further recommends that if such objections are made that the Court should remand this action to the Magistrate for further consideration. Under Rule 72(b) of the Federal Rules of Civil Procedure, any party has ten (10) days from receipt of this Report and Recommendation in which to file any written objections to this Recommendation, with the District Court. Any party opposing said objections shall have ten (10) days from receipt of any objections filed to this Report in which to file any responses to said objections. Failure to file specific objections within ten (10) days of receipt of this Report and Recommendation can constitute a waiver of further appeal of this Recommendation. *Thomas v. Arn*, 474 U.S. 140, 106 S.Ct. 466, 88 L.Ed.2d 435 (1985), *reh'g denied*, 474 U.S. 1111 (1986).

Entered this the 19th day of March, 1992.

(signed)
WILLIAM J. HAYNES, JR.
United States Magistrate Judge

Supreme Court, U.S.
FILED
FEB 22 1994
OFFICE OF THE CLERK

No. 93-1172

In The

Supreme Court of the United States

October Term, 1993

JAMES ALBERT ELKINS, SR., MARY JO ELKINS,
as parents and natural guardians of
JAMES ALBERT ELKINS, II,

Petitioners,

v.

RICHARDSON-MERRELL, INC.,

Respondent.

Petition for Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit

BRIEF OF RESPONDENT RICHARDSON-MERRELL, INC. IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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February 21, 1994

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OR CALL COLLECT (402) 342-2831

CORPORATE AFFILIATIONS OF RESPONDENT

Respondent, Richardson-Merrell, Inc., now known as Merrell Dow Pharmaceuticals Inc., is a wholly-owned subsidiary of Marion Merrell Dow Inc., which is approximately two-thirds owned by The Dow Chemical Company. Their subsidiaries and affiliates which have securities in the hands of the public are the following:

The Dow Chemical Company
Arabian Chemical Company Limited
Arabian Chemical Company (Latex) Limited
DowBrands L.P.
DCU/LB Trust
Destec Energy, Inc.
Dexco Polymers
Dow Chemical Iberica S.A.
Fort Saskatchewan Ethylene Storage Limited Partnership
H-D Tech Inc.
Cromarty Petroleum Company Limited
Petroquimica-Dow S.A. (Petrodow)
Dow Chemical Japan Limited
Ulsan Pacific Chemical Corporation
Epoxital S.R.L.
Safechem Umwelt Service GmbH
Dow Corning Corporation
Marion Merrell Dow Inc.
Fort Saskatchwan Ethylene Storage Corporation
Promix System
Dow Kakoh Kabushiki Kaisha
Dow Mitsubishi Kasei Limited
Dow Quimica Argentine S.A.
Anticorrosivos Industriales Limitada
Dow-United Technologies Composite Products Inc.

CORPORATE AFFILIATIONS OF RESPONDENT – Continued

El Dorado Terminals Company
Expandite Essex Pty. Limited
Gurit-Essex A.G.
Etoxilados del Plata S.A.
H.D. Polyurethane Company
Joliet Marine Terminal Trust Estate
Lucky Epoxy Limited
Marisub V, Inc.
Carderm Capital L.P.
Marion Merrell Dow K.K.
P.T. Dow Polymers Indonesia
MDP Holdings Ltd.
P.T. Pacific Indomas Plastic Indonesia
Airco Generon Systems LP
DH Compounding Company
DowElanco
Tritech International
Dow Elanco B.V.
P.T. Pacific Chemicals Indonesia
Generon Systems
Generon Systems A.G.
Sumitomo Dow Limited
Zhejiang Pacific Chemical Corporation

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APPENDIX D

Decision of the United States Court of Appeals for the Sixth Circuit in *Lee v. Richardson-Merrell, Inc.*, No. 91-5369, *slip op.* (6th Cir. April 22, 1992), 961 F.2d 1577 (table), 1992 W.L. 92750, *cert. denied*, ___ U.S. ___, 113 S.Ct. 197 (1992) A17

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Fed.R.Civ.P. 56(c) 4, 5, 6, 7, 9, 10

MISCELLANEOUS:

Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 Hastings L.J. 301 (1992) 2

Sheffield, et al., *"The Creation of Therapeutic Orphans – or What Have We Learnt From The Debendox Fiasco,"* 143 Med. J. Australia 143 (1985) 2

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COUNTER-STATEMENT OF THE CASE

Within the past two years, the Sixth Circuit has twice addressed the quantum of evidence required before a Bendectin plaintiff meets his burden of proof requiring submission of his case to a jury. *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349 (6th Cir.), *cert. denied*, ___ U.S. ___, 113 S.Ct. 84 (1992); *Lee v. Richardson-Merrell, Inc.*, No. 91-5369, *slip op.* (6th Cir. April 22, 1992), 961 F.2d 1577 (table), 1992 W.L. 92750, *cert. denied*, ___ U.S. ___, 113 S.Ct. 197 (1992) (attached hereto as Appendix D).[1] In each of these cases, the Sixth Circuit concluded that the evidence proffered by those plaintiffs was "simply inadequate . . . [to] permit a jury to conclude that Bendectin more probably than not causes limb defects." *Turpin*, 959 F.2d at 1360.[2] The Sixth Circuit in this case reached the same conclusion based upon evidence identical in all material respects to that which was submitted by plaintiffs in the earlier cases. (A2, n.1)

I. Merrell Dow Pharmaceuticals Inc. ("Merrell Dow") manufactured and marketed Bendectin from 1956 to 1983.

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[1] Because the Sixth Circuit's Opinion in *Lee* is unpublished, Respondent has provided a copy of the Opinion in an Appendix to its Brief. Respondent has continued the numbering of this Appendix as if it continues from Petitioners' Appendix. Petitioners' Appendix is incorporated by reference herein so that citations to A1-A16 are to Petitioners' Appendix. All other cites are to Respondent's Appendix.

[2] *See also, Lee v. Richardson-Merrell, Inc.*, at A20:

> We conclude that a finding of a causal relationship between Bendectin use and Michael Lee's birth defects based upon this evidence would be conjectural at best in light of this court's recent opinion in *Turpin* . . . .

Bendectin was an antinauseant, available only by prescription, for use by pregnant women to treat "morning sickness," the nausea and vomiting frequently associated with pregnancy.

As the leading treatment for morning sickness, Bendectin was prescribed in as many as 25% to 30% of all United States pregnancies. An estimated 33 million women world-wide took Bendectin during pregnancy. This broad and long term use of the product, combined with the common occurrence of birth defects in the general population, assured, merely as a matter of background incidence, that many women who had taken Bendectin would bear children with birth defects.[3] These events spawned a monumental tort litigation.[4] Because of enormous litigation costs, Merrell Dow ceased producing Bendectin in 1983, despite the fact that it was, and still is approved for marketing by the Food and Drug Administration.[5]

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[3] *Sheffield*, et al., *"The Creation of Therapeutic Orphans – or What Have We Learnt From The Debendox Fiasco,"* 143 *Med.J. Australia* 143 (1985). In Australia and England, Bendectin was known as Debendox.

[4] *See Turpin v. Merrell Dow Pharmaceuticals Inc.*, 959 F.2d 1349, 1351-52 (6th Cir.), *cert. denied*, 113 S.Ct. 84 (1992); Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 Hastings L.J. 301, 318-320, 398-401 (1992).

[5] In 1980, the FDA's Fertility and Maternal Health Drugs Advisory Committee, after studying the relevant literature and conducting a full hearing on the issue, concluded that "there was no increased incidence of birth defects among Bendectin-exposed infants; that there was no need for further animal or epidemiological studies; and that Bendectin should not be withdrawn from the market." The FDA adopted these findings. *See*

II. Petitioners commenced this action in 1990 contending that Mary Jo Elkins'[6] use of the antinauseant drug Bendectin during 1968 and 1969 caused her son, James Albert Elkins, II, to be born with deformities of the metacarpals in both hands and the absence of his lower limbs. At the time Mrs. Elkins was prescribed Bendectin, she also received a prescription for Mycostatin, an antifungal antibiotic, to treat a vaginal infection. Shortly thereafter, an additional medicine, Thorazine, was prescribed to further treat her nausea and vomiting. (JA 69).

After extensive discovery, Merrell moved for summary judgment, contending that there was no admissible evidence sufficient to raise a triable issue of fact as to whether Bendectin causes birth defects in general or, specifically, caused James Elkins, II's birth defects. (JA 70, 98). Merrell supported its motion with summaries of 35 human epidemiology studies published in the world's scientific and medical literature, none of which found a causal connection between Bendectin use and birth defects (JA 111-133), as well as documents from the Food and Drug Administration (JA 134-146)[7] and the Affidavit of Steven Lamm, M.D. (JA 105-110), both of which concluded that there was no causal connection between

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Richardson v. Richardson-Merrell Inc., 857 F.2d 823, 824, 827 (D.C. Cir. 1988), *cert. denied*, 493 U.S. 882 (1989).

[6] James Albert Elkins, Sr. and Mary Jo Elkins were originally individual parties in this action. Their claims, however, were dismissed with prejudice by stipulation. (A-10).

[7] The FDA documents consisted of the following: FDA Drug Bulletin, Vol. 11, No. 1 (March 1981); FDA Talk Paper, T79-49 (October 1, 1979); FDA Talk Paper, T80-40 (September 17, 1980) and; FDA Talk Paper, T82-45 (June 29, 1982).

Bendectin use and an increased incidence of birth defects. Merrell also cited (and in some instances provided copies of) numerous previous decisions rendered in other Bendectin cases including the opinion in the *Lee* case rendered by the United States District Court for the Western District of Tennessee (JA 88-89), together with Petitioners' motion to consolidate this case with *Lee* which Petitioners admitted involved identical issues of causation and the same expert witnesses. (JA 147-154). Finally, Merrell supplied excerpts of previous testimony of a number of Petitioners' expert witnesses.[8]

Petitioners' opposition to Merrell's motion consisted of a Memorandum of Points and Authorities which was more than 100 pages in length.[9] (JA 158-274). Petitioners did not dispute the accuracy of the summaries supplied by Merrell or the admissibility of *any* of its materials. Petitioners instead supplied several affidavits of purported experts who concluded that Bendectin is capable of causing birth defects.[10]

On March 19, 1992, Magistrate William J. Haynes, Jr., after careful review of the material presented by the

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[8] Excerpts of testimony were provided for, among others, Drs. Palmer and Crescitelli. Memorandum of Law in Support of Defendant Merrell Dow's Motion for Summary Judgment, dated June 21, 1991, at Exhibits 2, 11, 13 and 14. *See, e.g.*, JA 155-156.

[9] Despite the length of this pleading, Petitioner nowhere raises his current assertion that Merrell failed to meet its initial burden under Rule 56(c). Fed.R.Civ.P. 56(c).

[10] These affidavits were, in all material respects, identical to those filed in prior Bendectin cases including *Lee* and *Turpin*.

parties, recommended that Merrell's motion be granted.[11] (JA 50-52). On July 31, 1992,[12] the district court adopted the recommendation. After consideration of the Magistrate's recommendations and the supplemental pleadings filed by the parties, the court held that there was insufficient evidence upon which a reasonable jury could base a finding in favor of plaintiff. (A10-A13).

III. After the original briefing was completed, this Court handed down its decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, ___ U.S. ___, 113 S.Ct. 2786 (1993). Merrell advised the Sixth Circuit of the *Daubert* decision.[13] Petitioner then filed a supplemental "letter brief" arguing, for the first time, that Merrell failed to satisfy its threshold burden to show an absence of a genuine issue of material fact under Rule 56(c). Fed.R.Civ.P. 56(c).

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[11] The District Court had previously referred Merrell's motion to the Magistrate pursuant to 28 U.S.C. § 636 (b)(1)(B). (JA 99).

[12] Prior to the district court's ruling, but before the briefing was completed, the Sixth Circuit affirmed the grant of summary judgment in the *Lee* case (A17). Thus, Plaintiffs' Supplement to his Memorandum of Law in Opposition to Defendant Merrell Dow Pharmaceuticals Inc.'s Motion for Summary Judgment, filed June 2, 1992 (JA 418-420), attempted to address the applicability of the Sixth Circuit's affirmance to Merrell's then pending motion.

[13] In particular, Merrell noted that this Court cited the *Turpin* decision with approval when referring to a trial court's power to use "conventional devices", such as summary judgment, when it determines that "evidence presented supporting a position is insufficient to allow a reasonable juror to conclude that the position more likely than not is true . . . ." 113 S.Ct. at 2798.

In affirming the decision of the district court, the Sixth Circuit ruled that because Petitioners bore the ultimate burden of persuasion on the issue of causation at trial, Merrell was required only to "point out" or "show" the lack of a genuine issue regarding causation.[14] (A5). To meet this burden of "pointing out" or "showing" the lack of a genuine issue, Merrell "had no obligation to support its motion with any affidavits . . . so long as whatever is before the district court demonstrates" the lack of a genuine issue. *Id., citing, Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). After reviewing the voluminous record before the district court, the Sixth Circuit specifically held that "Merrell pointed out the absence of a genuine factual issue on the material element of causation." (A6). Having determined that Merrell's initial burden was met, the Sixth Circuit then reviewed the district court's determination that Petitioners failed to meet their corresponding burden and agreed that Petitioners "failed to demonstrate the existence of a genuine factual dispute regarding causation." (A6).

SUMMARY OF THE ARGUMENT

Petitioners attack the circuit court's ruling on a purely procedural ground raised for the first time at the circuit court level. They contend that the Sixth Circuit erroneously determined that Respondent had met its burden, under Rule 56(c), to "show that there is no genuine

[14] The Sixth Circuit did, however, hold that other issues presented by the Petitioners' were, in fact, waived for failure to raise them in the district court. *See* A7.

issue as to any material fact and that [Merrell] is entitled to judgment as a matter of law . . . . " Fed.R.Civ. P. 56 (c). They allege that the Sixth Circuit found the burden met by a mere "conclusory assertion" that Petitioners could not show an essential element of their case, i.e., causation. But this contention misstates the record before the circuit court, the Sixth Circuit's holding and plainly presents no issue warranting certiorari. As this Court made clear in *Celotex*, a party moving for summary judgment must "show" rather than merely "state" the absence of a genuine issue of material fact. That showing, however, far from requiring submission of affirmative evidence, can be made by identifying the materials in the record, including the non-moving party's materials, demonstrating the non-movant's inability to meet the burden which it faces at trial. *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986). In other words, the standard requires the moving party to do the work of *identifying* the relevant record material. Not surprisingly, the decision of the Fourth, Fifth and Eleventh Circuits cited by Petitioner (Pet. at 2) say nothing different.[15]

Quite simply, nothing in the Sixth Circuit's opinion (or in any other circuit courts' opinion cited by Petitioner) repudiates or departs from that standard. Nor, in fact, does the Sixth Circuit's earlier decision in *Street*, which,

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[15] Notwithstanding Petitioners' contentions, the Court of Appeals for the District of Columbia did not adopt any different standard for Rule 56 in *ACLU Foundation of Southern California v. Barr*, 952 F.2d 457 (D.C. Cir. 1991). Rather, the circuit court addressed, in *dicta*, the certain special problems associated with intelligence information relating to surveillance under the Foreign Intelligence Surveillance Act, 50 U.S.C. §§ 1801-1811.

in any event, was not cited in this case on the legal standard governing summary judgment.[16] Accordingly, this case presents only a fact specific application of established summary judgment standards – an issue unworthy of this Court's attention.

ARGUMENT

I. This Court Should Deny *Certiorari* Because This Case Does Not Present Issues Upon Which There Is Conflict Among The Circuit Courts.

Petitioners' contend this Court's decision in *Daubert* requires a finding that the sole affidavit filed in support of Merrell's motion for summary judgment (that of Dr. Lamm) be held inadmissible. Since, according to Petitioners, Merrell's motion is unsupported by other record evidence, Merrell's motion essentially consists of a "mere conclusory assertion" that Petitioners cannot prove their case. *Petition* at 4. According to Petitioners, the Sixth Circuit nevertheless granted Merrell's motion because it allegedly reads *Celotex* as permitting a movant to merely assert the nonmoving party cannot produce sufficient

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[16] The Sixth Circuit did cite *Street v. J.C. Bradford & Co.*, 886 F.2d 1472 (6th Cir. 1989) in resolving Petitioners' argument that the district court's grant of summary judgment violated their right to a jury trial guaranteed by the Seventh Amendment (A8) – an argument not presented by this Petition. In doing so, the Sixth Circuit merely approved this Court's direction in *Matsushita Elect. Indus. Co.,-Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) "to consider the record as a whole on summary judgment and decide whether any rational juror could decide the disputed factual issue in the nonmovant's favor." (A8).

evidence to go to a jury and thereby challenge the non-movant to "put up or shut up" on a critical issue. *See Petition* 1-2, *citing, Street v. J. C. Bradford & Co.*, 886 F.2d 1472, 1478 (6th Cir. 1989).

In discussing and resolving Petitioners' challenge under *Daubert*, to Merrell's alleged failure to meet its Rule 56(c) burden, the Sixth Circuit neither mentions nor relies upon the *Street* "put up or shut up" approach. (A5-A6) Thus, this case does not present a vehicle for determining the soundness of an alleged "put up or shut up" approach.

In fact, Merrell's motion in this case was obviously supported by far more than a "mere conclusory assertion" that plaintiffs could not prove their case. The motion was amply supported by the Lamm affidavit, the FDA documents, the summaries of the published literature, other opinions and Petitioners' own admission that their causation evidence was the same as that which was proffered in the *Lee* and *Turpin* cases, an admission that the Sixth Circuit specifically confirmed. A2, n.1. (". . . identical in all material respects to the evidence . . . [in *Turpin*]").

Even the admission by itself – specifically listed as a type of evidence proper under Rule 56(c) – would be enough to sustain Merrell's burden. *See*, 10A C. Wright, A. Miller & M. Kane, Federal Practice and Procedure § 2724, pp. 52-54 (2nd ed. 1983) (hereinafter "Wright & Miller").[17] But, it is clear that *all* of the material was

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[17] "Rule 56(c) also permits the court to consider any admission on file. The quoted words make it clear that the admissions

properly part of Merrell's showing. *See Celotex*, at 323 ("whatever is before the district court"); Wright & Miller, §§ 2721, at p. 40,[18] § 2724, at p. 73.[19]

The Sixth Circuit was therefore correct in readily concluding that Merrell met its burden under Rule 56 to show on the record that Petitioners had insufficient evidence to meet their burden of proving causation.

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need not be pursuant to rule 36: they may have emerged at the pretrial conference, have occurred during the oral argument on the motion, have been made in connection with one of the other discovery procedures or have their roots in a joint statement or stipulation of counsel."

[18] ("[T]he particular forms of evidence mentioned in [Rule 56] are not the exclusive means of presenting evidence on a Rule 56 motion.")

[19] ("The cases indicate that there are a variety of materials not expressly mentioned in Rule 56 that a federal court may consider on a summary judgment motion") (citations omitted).

CONCLUSION

The petition for writ of *certiorari* should be denied.

Respectfully submitted,

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APPENDIX D

NOT FOR PUBLICATION

No. 91-5369

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

RONNIE LEE and MACKEY LEE, Individually and as Parents and Natural Guardians of MICHAEL LEE, a Minor,

Plaintiffs-Appellants,

v.

RICHARDSON-MERRELL, INC., A Delaware Corporation,

Defendant-Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF TENNESSE [sic]

(Filed Apr. 22, 1992)

NOT RECOMMENDED FOR FULL-TEXT PUBLICATION

Sixth Circuit Rule 24 limits citation to specific situations. Please see Rule 24 before citing in a proceeding in a court in the Sixth Circuit. If cited, a copy must be served on other parties and the Court. *This notice is to be prominently displayed if this decision is reproduced.*

BEFORE: MARTIN and SUHRHEINRICH, Circuit Judges; and PECK, Senior Circuit Judge.

PER CURIAM. This is an appeal in a diversity action brought under Tennessee law by plaintiffs Ronnie and

Mackey Lee on behalf of their minor child, Michael Lee, against defendant Richardson-Merrell, Inc. ("Merrell"). The Lees contend that Michael's birth defect, a limb reduction defect, was caused by his mother's ingestion during pregnancy of the Merrell product Bendectin. The district court granted summary judgment in favor of Merrell. We affirm.

The plaintiffs allege that Mackey Lee ingested the anti-nausea drug Bendectin on or about September 21, 1973, when she was about seven weeks pregnant with Michael Lee. Michael was born on March 27, 1974, with various limb deformities characterized by shortness and webbing of his fingers and generalized smallness of his hands. The Lees assert that Mackey Lee ingested no other drugs during this period of time that Michael's birth defects are not genetic. The plaintiffs submit that Mackey Lee's ingestion of Bendectin during the time that Michael's limbs were beginning to develop was the proximate cause of Michael's birth defects.

Merrell filed a motion for summary judgment alleging that all relevant epidemiological studies indicate that there is no statistically significant link between the use of Bendectin and the type of birth defects suffered by Michael Lee. Merrell asserted that these human epidemiological studies comprised the only competent evidence on the issue of whether Bendectin is a teratogen (a substance capable of causing birth defects).

The Lees submitted contrary scientific testimony which concluded that Bendectin was a teratogen based on (1) chemical structure analyses of Bendectin's antihistamine component doxylamine succinate; (2) *in vitro*

(test tube) studies; (3) *in vivo* (animal) studies; and (4) criticism and reanalysis of various epidemiological studies submitted by Merrell. The Lees argued that their scientists possessed the requisite "knowledge, skill, training, education,and experience" to qualify as experts and that their opinions were based on "the type of data generally and reasonably relied upon by experts in the particular field."

After a thorough review of the proffered testimony, the district court determined that the Lees had not produced sufficient evidence of causation to preclude summary judgment. The appeal followed.

The Lees offered the opinion of seven experts to establish that Bendectin was a teratogen and that Mackey Lee's ingestion of Bendectin caused Michael Lee's birth defects. These scientists possess expertise in fields ranging from developmental biology and reproductive epidemiology to biostatistics and pharmacology. Collectively, the Lees' experts would offer testimony concluding that to a reasonable degree of certainty Bendectin is a associated with limb defects.

In response to this expert testimony, defendant Merrell submits that human epidemiological studies demonstrate an absence of any significant causal link connecting Bendectin use with birth defects. To support this position, Merrell submitted summaries of over thirty epidemiologic studies, none of which demonstrate a connection between Bendectin and birth defects.

As noted above, the Lees' experts rely on chemical structure analyses of doslyamine succinate, *in vitro* and *in vivo* studies and reanalyses of human epidemiological

data. We conclude that finding of a causal relationship between Bendectin use and Michael Lee's birth defects based upon this evidence would be conjectural at best in light of this court's recent opinion in *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, No. 90-5690 (6th Cir. March 11, 1992). In *Turpin*, another panel of this court reviewed the scientific data on Bendectin in great detail and concluded that the evidence presented by the plaintiffs' experts fell short of showing that "Bendectin more probably than not causes limb defects in children born to mothers who ingested the drug at prescribed doses during pregnancy." Slip op. at 24.

The evidence presented by the Lees in the instant case is identical in all material respects to the evidence relied upon by the plaintiffs in *Turpin*. *Compare* Jt. App. 2040-2092 (Affidavits of Drs. Glasser, Gross, Crescitelli and Swann) *with Turpin*, slip op. 9-22 (identical testimony by affidavit). The plaintiffs' experts in both cases are the same. In both cases, the experts reach their conclusions based upon their reanalyses of prior epidemiological studies and the use of animal studies to predict Bendectin's teratogenic effects in human beings. For the reasons stated in *Turpin*, we view this testimony as unable to bridge "[t]he analytical gap between the evidence presented and the inferences to be drawn on the ultimate issue of human birth defects. . . . " Slip. op. at 24. In short, the plaintiffs' scientific evidence, taken as whole, fails to create a genuine issue of material fact. Consequently, summary judgment for the defendant on the issue of causation was appropriate. *See Street v. J.C. Bradford & Co.*, 886 F.2d 1472, 1479 (6th Cir. 1989) (respondent must

produce evidence supporting every essential element of his or her case to prevent summary judgment).

We have examined the entire record in this case and we can find no material difference between this case and *Turpin*. We further find that without such evidence the plaintiffs cannot prove that Michael Lee's birth defects were caused by his mother's ingestion of Bendectin. Given this conclusion we need not address Merrell's remaining arguments or the district court's alternative holding excluding plaintiffs' evidence. Accordingly, for the reasons as fully stated in this court's opinion in *Turpin*, the district court's grant of summary judgment in favor of defendant Merrell is AFFIRMED.

A TRUE COPY

Attest:

LEONARD GREEN, Clerk

By /s/ Diane Schnur
Deputy Clerk

Supreme Court, U.S.
FILED
FEB 28 1994
OFFICE OF THE CLERK

(3)

No. 93-1172

IN THE

Supreme Court of the United States

October Term, 1993

JAMES ALBERT ELKINS, SR.; MARY JO ELKINS, as parents and natural guardians of JAMES ALBERT ELKINS, II,

Petitioners,

v.

RICHARDSON-MERRELL, INC.,

Respondent.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

REPLY BRIEF FOR PETITIONERS

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REPLY TO BRIEF IN OPPOSITION

The parties in this case are in agreement that serious confusion and conflict exist among the lower federal courts over the proper interpretation of *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986), concerning the nature of a movant's burden on a summary judgment motion. As explained by the Petition ("Pet.") at 7, and as respondent Merrell nowhere contests, these problems emanate from a single paragraph in the majority opinion in *Celotex*. The beginning of the paragraph states that the movant "always bears the initial responsibility of . . . identifying those portions of 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,' which it believes demonstrate the absence of a genuine issue of material fact." *Id.* at 323 (quoting Rule 56(c)). But the end of the paragraph states that summary judgment may be granted on the basis of "whatever is before the district court." *Id.*

What is a movant's burden under *Celotex*? Must a movant "show," by reference to one or more of the five record items listed in Rule 56(c), that no genuine factual issue on a given point exists? Or, does the idea that summary judgment may be granted based on "whatever is before the district court" permit the movant to satisfy its burden based on materials *outside* the record?[1] Is a district court to grant summary judgment for

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[1] For example, in its opposition Merrell suggests for the first time in the course of this three-year-old proceeding that it satisfied its burden because its summary judgment brief and attachments to that brief: (1) provided summaries of 35 human epidemiology studies published in the world's scientific and medical literature," (2) provided "documents from the Food and Drug Administration," (3) "cited (and in some instances provided copies of) numerous previous decisions rendered in other Bendectin cases," and (4) "supplied excerpts of previous testimony of a number of Petitioners' expert witnesses" — that is, *two* of petitioners' *six* expert witnesses (without relating that previous testimony to the facts of this case). Brief of Respondent Richardson-Merrell, Inc. in Opposition to Petition for Writ of Certiorari ("Opp.") at 3-4 & n.8; *see also* Opp. at 9. None of these four items is of the type listed in Rule 56(c).

Whether or not such materials *if considered by the district court in assessing Merrell's burden as movant* would in fact support Merrell's view about the safety of Bendectin is irrelevant to the Petition, which addresses a purely legal issue about the meaning of *Celotex*. Such factual details would be considered only on remand, if Merrell persuaded this Court to construe

reasons that were never advanced in the motion, and that the nonmovant was never permitted to address in the opposition?[2]

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expansively the reference in *Celotex* to "whatever is before the district court." Therefore, petitioners will not address Merrell's gratuitous statements about the asserted harmlessness of Bendectin. *See* Opp. at 1-4.

[2] For example, in this case Merrell makes much of the fact that *after* it filed its summary judgment motion, the Sixth Circuit held in two other Bendectin cases that *the plaintiffs* in those cases had not mustered sufficient admissible evidence to defeat Merrell's summary judgment motion. *See* Opp. at 1, 9. This is hardly news. The petition forthrightly noted that the causation evidence petitioners put forward in their summary judgment opposition is similar to that presented by the earlier plaintiffs and, "[o]n the strength of [these two Sixth Circuit cases], the district court held that Elkins' expert affidavits on causation were insufficient to defeat summary judgment. The Sixth Circuit agreed with this holding, a point on which Elkins does not now seek review in this Court." Pet. at 3 n.4 (citations omitted). Merrell falsely suggests that petitioners' decision to set aside issues concerning the admissibility and sufficiency of the evidence *they* submitted under Rule 56(e) in opposing summary judgment, in the aftermath of two intervening Sixth Circuit decisions finding problems with that evidence, constitutes some sort of "admission" that Merrell met its threshold Rule 56(c) burden. But Merrell's motion did not reference those two Sixth Circuit decisions or any supposed "admission" based on them (as those decisions were announced well after Merrell filed its motion), petitioners had no opportunity to conform their experts' affidavits to those decisions, and hence those decisions are necessarily irrelevant to whether Merrell met its initial burden.

More importantly, to construe the "whatever is before the district court" passage in *Celotex* to mean that whether *the movant* has met its threshold burden depends in part on the adequacy of *the non-movant's* submission, as Merrell urges and as many lower federal courts apparently accept, works a radical transformation of settled principles. This Court's past decisions demonstrate that the nature of plaintiffs' proof in opposition to summary judgment is simply irrelevant to the issue presented here: whether the *movant* has met its initial burden under 56(c). For example, in *Adickes v. S.H. Kress & Co.*, 398 U.S. 144 (1970), this Court noted that the plaintiff had failed to satisfy Rule 56(e), because her summary judgment opposition had contained no admissible evidence on the issue in question, *id.* at 159 & n.19 (response consisted of only "hearsay" and "unsworn" statements); nevertheless, this Court denied summary judgment because the defendant had not discharged its *own* burden "under Rule 56(c) to show initially the absence of a genuine issue." *Id.* at 159-60. No Justice in *Celotex* disagreed with the principle that "[i]f the moving party has not fully discharged this initial burden of production, its motion for summary judgment must be denied, and the Court need not consider whether the moving party has met its ultimate burden of persuasion." *Id.* at 332 (Brennan, J., joined by Burger, C.J., and Blackmun, J., dissenting).

The majority opinion in *Celotex* does not resolve these fundamental points. That opinion simply did "not clearly explain[] what is required of a moving party seeking summary judgment on the ground that the non-moving party cannot prove its case." *Id.* at 329 (Brennan, J., joined by Burger, C.J., and Blackmun, J., dissenting).

The confusion about the meaning of *Celotex* that was predicted by three Justices, *see id.*, has fully emerged. Although several circuits have followed the explicit recognition of four Justices in *Celotex* that a movant must always "show" that no genuine issue exists, based on the record materials listed in Rule 56(c) (*see* Pet. at 7 n.8), for the most part this point has not been followed by the lower federal courts. *See* Pet. at 2, 7-8. The failure to require movants to identify precise factual defects in the record obviously creates a huge incentive to file blunderbuss summary judgment motions, often forcing complete "paper trials" that serve no real purpose and waste significant judicial and private resources. *See* Pet. at 9.

Obviously, at the earliest opportunity this Court should resolve the confusion over *Celotex* which has now festered for eight years. Thus the primary issue at this juncture is whether some factual or procedural aspect of this case disqualifies it as a suitable vehicle for revisiting *Celotex*. If not, it would be inadvisable to decline review in the hope that before too long another litigant will have the persistence and the resources to pursue this issue through the lower courts and present it in a fashion adequate for this Court's review.

It would be hard to imagine a more suitable case than this one for resolving the purely legal issue of the meaning of the key confusing paragraph in the *Celotex* majority opinion. Here, Merrell conceded below and has conceded in this Court that "[t]he only item on th[e] list" of relevant record items in Rule 56(c) presented with its motion was an affidavit that is obviously inadmissible because the epidemiologist used an invalid scientific

methodology to produce his conclusion. Pet. at 3-4 & n.5;[3] *see also* note 1, *supra*. Merrell agrees with petitioners (*see* Pet. at 5, 7) that the Sixth Circuit below found that Merrell had met its burden based on the key, "whatever is before the district court" passage of the *Celotex* majority opinion. *See* Opp. at 6, 10.

Further, the parties have defined starkly divergent legal positions, promising a solid and informative clash over the core meaning of Rule 56(c) as it defines a movant's burden on summary judgment. Petitioners, backed by the opinions of four Justices in *Celotex* and perceptive opinions of the Fifth and Eleventh Circuits, argue that Rule 56(c) means what it says, and forces movants to meet their burden based on five identified types of record material. *See* Pet. at 2, 6-7. Merrell, citing the "whatever is before the district court" passage of *Celotex* and one academic treatise, urges that a whole range of material, nowhere listed in Rule 56(c), is properly considered in evaluating whether a movant has met its burden. Opp. at 9-10. Regardless of which set of arguments is most plausible, it is clear that review of this case is essential to resolve the confusion over *Celotex* and

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[3] Merrell cites this affidavit in passing (Opp. at 3, 9) but makes no suggestion that the affidavit is even conceivably admissible under the standards laid out by *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786 (1993), and does not deny that it "made no response, either in writing or at oral argument, to [petitioners'] detailed demonstration of the invalidity of the methodology used by [Merrell's] only expert." Pet. at 4 n.5.

Merrell does intimate, without actually arguing, that petitioners should have raised the Rule 56(c) issue sooner, noting that in the district court opposition "[p]etitioner nowhere raise[d] his current assertion that Merrell failed to meet its initial burden under Rule 56(c)," Opp. at 4 & n.9, and complaining that only in petitioners' supplemental letter brief did petitioners argue, "for the first time, that Merrell failed to satisfy its threshold burden to show an absence of a genuine issue of material fact under Rule 56(c)." Opp. at 5. But the letter brief was duly filed within a month of this Court's decision in *Daubert*, which was the basis for objecting to the admissibility of Merrell's sole affidavit. In its *de novo* review of the propriety of summary judgment on this record, the Sixth Circuit was obliged to consider all applicable law, including the new *Daubert* standard. *Harper v. Virginia Dept. of Taxation*, 113 S. Ct. 2510, 2517 (1993). The Sixth Circuit did just that; it assumed that the affidavit was indeed inadmissible under *Daubert*, but based on its construction of *Celotex* it held that Merrell's failure to set forth any of the record materials listed in Rule 56(c) was irrelevant. *See* Pet. at 4-5. The question of the proper interpretation of Rule 56(c) is thus squarely presented by this case.

to ensure that the summary judgment rules are applied consistently throughout the nation.

CONCLUSION

For all these reasons, the Petition should be granted.

Respectfully submitted,

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